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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,994	10/30/2003	Lopa Mishra	P04470US02/BAS	7531

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,994	MISHRA, LOPA	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1*, 2, 13, drawn to a nucleic acid encoding an elf-1 protein, classified in class 536, subclass 23.5.

Group 2. Claims 1*, 2, 13, drawn to a nucleic acid encoding a liyor-1 (145) protein, classified in class 536, subclass 23.5.

Group 3. Claims 1*, 2, 13, drawn to a nucleic acid encoding a pk protein, classified in class 536, subclass 23.5.

Group 4. Claims 1*, 2, 13, drawn to a nucleic acid encoding a protein 106, classified in class 536, subclass 23.5.

Group 5. Claims 1*, 2, 13, drawn to a nucleic acid encoding a praja-1 protein, classified in class 536, subclass 23.5.

Group 6. Claims 1*-2, 13, drawn to a nucleic acid encoding an elf-2 protein, classified in class 536, subclass 23.5.

Group 7. Claims 1*-2, 13, drawn to a nucleic acid encoding an elf-3 protein, classified in class 536, subclass 23.5.

Group 8. Claims 1*-2, 13, drawn to a nucleic acid encoding an gene 20, classified in class 536, subclass 23.5.

Group 9. Claims 1*-2, 13, drawn to a nucleic acid encoding an gene 36, classified in class 536, subclass 23.5.

Group 10. Claims 1*-2, 13, drawn to a nucleic acid encoding an gene 41, classified in class 536, subclass 23.5.

Group 11. Claims 1*-2, 13 drawn to a nucleic acid encoding an gene 112, classified in class 536, subclass 23.5.

Group 12. Claims 1*-2, 13, drawn to a nucleic acid encoding an gene 114, classified in class 536, subclass 23.5.

Group 13. Claims 1*-2, 13, drawn to a nucleic acid encoding an gene 118, classified in class 536, subclass 23.5.

Group 14. Claims 1*-2, 13, drawn to a nucleic acid encoding an gene 129, classified in class 536, subclass 23.5.

Group 15. Claims 3*, 4-5, 14, drawn to an elf-1 protein, classified in class 530, subclass 351.

Group 16. Claims 3*, 4-5, 14, drawn to an elf-2 protein, classified in class 530, subclass 351.

Group 17. Claims 3*, 4-5, 14, drawn to an elf-3 protein, classified in class 530, subclass 351.

Group 18. Claims 3*, 14, drawn to a liyor 1 (145) protein, classified in class 530, subclass 351.

Group 19. Claims 3*, 14, drawn to a pk protein, classified in class 530, subclass 351.

Group 20. Claims 3*, 14, drawn to a protein 106, classified in class 530, subclass 351.

Group 21. Claims 3*, 14, drawn to a praja-1 protein, classified in class 530, subclass 351.

Group 22. Claims 7*-8*, drawn to a method of treating a disorder by administering an elf protein, class 514, subclass 2.

Group 23. Claims 7*-8*, drawn to a method of treating a disorder by administering a praja-1 protein, class 514, subclass 2.

Group 24. Claims 7*-8*, drawn to a method of treating a disorder by administering a liyor-1 (145) protein, class 514, subclass 2.

Group 25. Claims 7*-8*, drawn to a method of treating a disorder by administering a pk protein, class 514, subclass 2.

Group 26. Claims 7*-8*, drawn to a method of treating a disorder by administering protein 106, class 514, subclass 2.

Group 27. Claim 9, drawn to a method of for detecting colon cancer by testing for the presence of praja-1 protein, class and subclass undeterminable.

Group 28. Claims 10-12, drawn to a method of isolating genes coding for early developing liver proteins, class and subclass undeterminable.

Group 29. Claims 15*-20*, drawn to an antibody to a protein of SEQ ID NO:21, classified in class 530, subclass 387.9.

Group 30. Claims 15*-20*, drawn to an antibody to a protein of SEQ ID NO:22, classified in class 530, subclass 387.9.

Group 31. Claims 15*-20*, drawn to an antibody to a protein of SEQ ID NO:23, classified in class 530, subclass 387.9.

Group 32. Claims 15*-20*, drawn to an antibody to a protein of SEQ ID NO:24, classified in class 530, subclass 387.9.

Group 33. Claims 15*-20*, drawn to an antibody to a protein of SEQ ID NO:25, classified in class 530, subclass 387.9.

Group 34. Claims 15*-20*, drawn to an antibody to a protein of SEQ ID NO:26, classified in class 530, subclass 387.9.

Group 35. Claims 15*-20*, drawn to an antibody to a protein of SEQ ID NO:27, classified in class 530, subclass 387.9.

Group 36. Claims 15*-20*, drawn to an antibody to a protein of SEQ ID NO:28, classified in class 530, subclass 387.9.

*These claims embrace multiple patentably distinct embodiments.

Should any one of the Groups from 1-36 be elected, Applicant is required to select one polypeptide (one amino acid sequence) as set forth in a SEQ ID NO. Once one polypeptide sequence is selected, all other sequences will be withdrawn from consideration.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. 806.05 for Inventions that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons:

Inventions 1-14, 15-21, 29-36, are independent and distinct, each from the other, because they are compositions which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each material composition, which cannot be exchanged (e.g., the nucleic acid encoding a elf-1 protein cannot be exchanged for a nucleic acid encoding a elf-2, liyor-1 (145), pk or praja-1 protein since the proteins encoded by the nucleic acids are structurally and functionally different). The nucleic acids of inventions 1-14, can be used to make hybridization probes or can be used in gene therapy as well as in the production of the proteins of interest. The proteins of inventions 15-21 can be used as probes, or used therapeutically or diagnostically, e.g. in screening. The antibodies of inventions 29-36 can be used to obtain the specific nucleic acids encoding the proteins to which the specific antibodies were raised, and can also be used in diagnostics, e.g. as a probe in immunoassays.

Inventions 15-21 and 22-26 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of inventions 15-21 can be used as antigen for antibody production.

Inventions 5 and 27 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §

806.05(h)). In the instant case the nucleic acids of invention 5 can be used in the production of the specific protein of interest or in gene therapy.

Inventions 29-36 and 22-28 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions are not disclosed as capable of use together.

Inventions 1-14 and 22-26 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions are not disclosed as capable of use together.

Inventions 22-26 are independent and distinct, each from the other, because the methods are practiced with materially different products which are structurally and chemically different, the novelty of the inventions lying in the products being selected and not the processes. The only feature in common in inventions 22-26 is "the method of treatment", which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products. Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The products in the different Groups are physically, chemically and biologically distinct from each other, and if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of

elf protein with a method of treatment would not necessarily reveal art for an association of praja-1 protein with a method of treatment.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

3. ***Election of Species***

This application contains claims directed to the following patentably distinct species of disorders of the claimed invention:

For Groups 22-26, Applicants are required to elect one each of the following species of disorders selected from:

(i) cholestasis;

(ii) biliary stones;

(iii) liver obstruction;

(iv) stricture;

(v) primary biliary cirrhosis;

(vi) primary sclerosing cholangitis;

(vii) end stage liver disease;

(viii) hepatocellular carcinoma;

(ix) anhidrotic ectoderm dysplasia;

(x) degenerative neurological disorders;

(xi) anemia;

(xii) ataxia;

(xiii) hemochromatosis;

(xiv) sideroblastic anemia; and

(xv) spinocerebellar ataxia.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of disorder for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7-8 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz, Ph.D., J.D.
Primary Examiner
Art Unit 1646
September 2, 2005